SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Southern Implants® Cosmetic and Anatomical abutments
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Intended use
Southern Implants® dental implant abutments are intended to be used in the Maxilla or Mandible for supporting a prosthesis on endosseous implants in order to restore chewing function for the patient.

Intended user
Dental Technicians, Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users.

Intended environment
The devices are intended to be used in a clinical environment such as an operating theater or a dentist consultation room.

Intended patient population
This device is used in the dental restoration of partially or fully edentulous patients in the upper or lower jaw. Restorations may comprise, partial or full bridges, multi-unit cases and may be fixed or removable.

Description
These are pre-manufactured abutments connected direct to an endosseous implant for use as an aid in prosthetic rehabilitation. Cosmetic Abutments are single unit screw retained abutments, retained directly to an endosseous implant. The apical sections taper, which means they can be used for multiple unit restorations if parralalism is ideal. The scalloped collar is shaped to follow soft tissue contours providing better aestetic results, and acts as an antirotational function for single unit restorations. Angled cosmetic abutments are not to be used with Co-axis implants. The Cosmetic and Anatomical abutments are provided sterile; however, it will no longer be sterile after modification.

Indications for use
Southern Implants Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- replacing single and multiple missing teeth in the mandible and maxilla,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
- immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

Contraindications
Do not use in patients:
- who are medically unfit for dental implant procedures
- where adequate numbers of implants could not be placed to achieve full functional support of the prosthesis,
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6Al-4V), gold, palladium, platinum or iridium.
- who are under the age of 18, have poor bone quality, blood disorders, infected implant site, vascular impairment, uncontrolled diabetes, drug or alcohol abuse, chronic high dose steroid therapy, anti-coagulant therapy, metabolic bone disease, radiotherapy treatment.

Warnings
THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.
- For the safe and effective use of dental implants it is suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.
- Responsibility for proper patient selection, adequate training, experience in the placement of implants, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves / vessels and / or loss of supporting bone.

Cautions
New and experienced Implant users should do training before using a new system or attempt to do a new treatment method. Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (i.e. poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone and patients who had oro-facial radiotherapy.) Thorough screening of prospective implant candidates must be performed including:
- A comprehensive medical and dental history.
- Visual and radiological inspection to determine adequate bone dimensions, anatomical landmarks, occlusal conditions & periodontal health.
- Bruxism and unfavourable jaw relations must be taken into account.
- Proper pre-operative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- Minimizing the trauma to the host tissue increases the potential for successful osseointegration.
- Electro-surgery should not be attempted around metal implants, as they are conductive.

During surgery
Care must be taken that parts are not swallowed during any of the procedures, a rubber-dam application is recommended when appropriate. Care must be taken to apply the correct tightening torque of abutments and abutment screws.

Post-surgery
Regular patient follow-up, and proper oral hygiene must be achieved to ensure favourable long-term results.

Compatibility information
SI implants should be restored with SI components. In the SI range there are 5 implant connections, the implant code and connection type, can be identified by specific abbreviations in the product codes. Range ‘identifiers are summarised in table A.

Table A (*) is indicative of various lengths available.

Implant connection type	Compatible device	
	Non-Angled	Angled
External Hex (EX)	Parts labelled DN (*), DB (*), DBA (*) DBBB (*)	Parts labelled DBNS12, DBS12, DBS24, DBAS12, DBAS24, DBBBS12, DBBBS24
Tri-Nex (EL) (Lobe)	Parts labelled TCA-EL-(ø)	Parts labelled TCA12-EL-(ø), TCA24-EL-(ø)
Deep Conical (DC)	TCA-DC-(ø)	TCA12-DC(ø), TCA24-DC(ø)
Internal Hex (M)	Parts labelled TCA-M, (used with ø3.75, 4.20 & 5.00 mm platforms)	Parts labelled TCA12-M, TCA24-M, (used with ø3.75, 4.20 & 5.00 mm platforms)

Internal Hex Provata (M) (Z)	Parts labelled TCA-M, (used with ø4.0, 5.0 & 6.0 mm platforms)	Parts labelled TCA12-M, TCA24-M, (used with ø4.0, 5.0 & 6.0 mm platforms)
	Parts labelled TCA-Z, (used with ø7.0, 8.0 & 9.0 mm platforms)	N/A

Storage, cleaning & sterilisation

The implants, cover screws and healing abutments are supplied sterile (sterilised by gamma irradiation) and intended for single-use prior to the expiration date (see packaging label). Sterility is assured unless the container or seal is damaged or opened. If packaging is damaged do not use the product and contact your Southern representative/ or return to Southern Implants. Do not reuse implants, cover screws, temporary abutments and abutments. Re-using these components may result in:

- Damage on the surface or critical dimensions, which may result in performance and compatibility degradation.
- Adds the risk of cross-patient infection and contamination if single-use items are reused.

Southern Implants does not accept any responsibility for complications associated with reused components.

Cleaning and disinfection

An implant restoration is a single- or multiple-tooth implant crown, bridge or substructure, attached to a Southern Implants abutment or multiple abutments.

Before intraoral use the final restoration needs to be cleaned and disinfected, as per restorative material manufacturer's instructions.

Sterilisation

Southern Implants recommends the following procedure to sterilise the restoration prior to use:

Methods to sterilise the restoration and abutment screw

1. Pre-vacuum sterilisation method: Steam sterilise the abutments at 132°C (270°F) at 180-220kPa for 4 minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilisation must be used.
2. Pre-vacuum sterilisation method: Wrapped, steam sterilise at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilisation cycle.

NOTE: Users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

First clinical procedure Method 1

1. Select appropriate abutment and check occlusal clearance.
2. The abutment may be shortened to the correct occlusal height. Use copious irrigation if the abutment is prepared in the mouth to avoid heating of the abutment and the implant / bone interface. It is recommenced to trim the abutment outside the patient mouth.
3. Position the abutment on the implant making sure that the retentive elements of the implant / abutment connections are properly aligned.
4. Fix the abutment to the implant with the correct screw and appropriate driver (Table B). Torque the screw down to the value indicated in Table C.
5. Verify the correct seating of the abutment using a radiographic image.
6. Do not exceed the recommended torque value as this may result in failure of the screw, abutment or implant. Do not torque less than the recommended value, this may result in loosening of the abutment that can lead to abutment or implant failure.

Note: Cosmetic Abutments are manufactured with a scalloped edge providing an anti-rotational function. For the External Hex implant range the straight abutments do not have a scallop and an anti-rotational groove needs to be cut into it.

7. To prevent impression material going down the access whole it must be closed with wax or silicone prior to impression taking.
8. A closed tray impression is taken and a temporary crown fitted.

Laboratory procedure method 1:

1. Produce a working model with removable gingival mask.
2. Fabricate a crown or bridge using conventional casting techniques.
3. The final restoration is returned to the dentist.

Second Clinical procedure method 1

1. Remove the temporary restoration if applicable, and confirm screw torque.
2. Cement the final crown or framework using conventional procedures after sealing the access hole, make sure there is no excess cement.

First clinical procedure Method 2

1. Take an impression of the implant interface using the appropriate impression coping: Refer to individual product catalogues for product compatible accessories.

Laboratory procedure method 2:

1. Attach the laboratory analogue to the impression coping and produce a working model with removable gingival mask.
2. Attach the Abutment to the laboratory analogue and shorten the Abutment to the correct occlusal height.
3. Fabricate a crown or bridge using conventional casting techniques.
4. For cement retained prosthesis the cementation of the restoration will take place in the mouth.
5. For screw retained restorations the restoration can be cemented in the laboratory.

NOTE: Do not pack porcelain directly onto the Abutment. It serves as a post only.

Second Clinical procedure method 2:

Clinical procedures

The clinician receives the restoration from the laboratory.

1. Remove the healing abutments or temporary restorations.
2. Clean, disinfect and sterilize the restoration as described above.
3. Insert the restoration into the patient's mouth.
4. Position the restoration on the implant making sure that the retentive elements of the implant / abutment connections are properly aligned.

Table B

Driver type	External Hex	DC	Tri-Nex	Internal Hex	IT
1.22 mm / 1.27 mm Universal driver	✓	✓		✓	
1.22 mm hex driver	✓	✓			
1.27 mm hex driver				✓	
Unigrip driver	✓		✓		
Quad driver	✓			Gold screws only	
Blade driver	✓				
Torx driver					✓

5. Fix the abutment to the implant with the correct screw and appropriate driver (Table B). Torque the screw down to the value indicated in Table C.

Table C

Direct to Implant	Torque
Ext-Hex	
ø3.25, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32-40 Ncm
Tri-Nex	
ø3.5mm	32 Ncm
ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	32-40 Ncm
DC	
ø3.0 mm	15 Ncm
ø3.5, 4.0 mm	20 Ncm
ø5.0 mm	25-32 Ncm
Internal Hex (M-Series & Provata)	
ø3.75, 4.2, 5.0 mm M-Series	32 Ncm
ø4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm Provata Implant	32 Ncm

6. Verify the correct seating of the restoration using radiographic image.
7. Do not exceed the recommended torque value as this may result in failure of the screw, abutment or implant, do not torque less than the recommended value, this may result in loosening of the abutment that can lead to abutment or implant failure.
8. Close the screw access hole.
9. Cement the final prosthesis if applicable.

Clinical benefits
Through this procedure patients can expect to have their missing teeth replaced and/ or crowns restored.

Healing
The healing time required for osseointegration depends on the individual and treatment protocol. It is the responsibility of the practitioner to decide when the implant can be restored. Good primary stability will govern if immediate loading can be done.

Implant care and maintenance
Potential implant patients should establish an adequate oral hygiene regime prior to Implant therapy. Proper post operative oral hygiene and implant maintenance instructions must be discussed with the patient, as this will determine the longevity and health of the Implants. The patient should maintain regular prophylaxis and evaluation appointments.

Materials
Cosmetic and Anatomical abutment: Titanium grade 3 or 4
Abutment screws: Titanium alloy Ti-90%, Al-6%, V-4%

Gold Alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu-9%

Side effects
Potential Side Effects and Temporary symptoms: Pain, swelling, phonetic difficulties, gingival inflammation. More persistent symptoms: The risks and complications with implants include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) breakage of the implant and/or abutment; (3) loosening of the abutment screw and/ or retaining screw; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/ or fibroblasts; (7) formation of fat emboli; (8) loosening of the implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates; and (11) bone loss possibly resulting in revision or removal.

Breakage
Implant and abutment fractures can occur when applied loads exceed the tensile or compressive strength of the material. Potential overloading conditions may result from; deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing, clenching), loss or changes in dentition or functionality, inadequate prosthesis fit, and physical trauma. Additional treatment may be necessary when any of the above conditions are present to reduce the possibility of hardware complications or failure.

Changes in performance
It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

MR Conditional
Non-clinical testing and MRI simulations were performed to evaluate the dental implant system offered by Southern Implants. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an implant from a Southern Implants System can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg and head average SAR of 3.2 W/kg, for 15 minutes of scanning (i.e., per pulse sequence) in the normal operating mode

The scanning conditions defined above will produce a maximum temperature increase of 4.9 °C in implants from Southern Implants systems after 15 minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by implants from Southern Implant System extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

Disposal
Disposal of the device and its packaging; Follow local regulations and environmental requirements, taking different contamination levels into account. When disposing of spent items, take care of sharp drills and instruments. Sufficient PPE must be used at all times.

Disclaimer of liability
This product is part of the Southern Implants product range and should only be used with the associated original products and according to the recommendations as in the individual product catalogues. The user of this product has to study the development of the Southern Implants product range and take full responsibility for the correct indications and use of this product. Southern Implants does not assume liability for damage due to incorrect use. Please note that some Southern Implants products may not be cleared or released for sale in all markets.

Notice regarding serious incidents
Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device and the competent

authority in the member state in which the user and / or patient is established.
The contact information for the manufacturer of this device to report a serious incident is as follows: sicomplaints@southernimplants.com

Basic UDI

Product	Basic-UDI Number
Basic-UDI for Metal Abutments	600954403872

Related literature & catalogues

CAT-2004- Tri-Nex Implants Product Catalogue
CAT-2005- IT Product Catalogue
CAT-2020- External Hex Implants Product Catalogue
CAT-2042- Deep Conical Implants Product Catalogue
CAT-2043- Internal Hex Implants Product Catalogue
CAT-2060- PROVATA® Implants Product Catalogue
CAT-2069- INVERTA® Implants Product Catalogue
CAT-2070- Zygomatic Implants Product Catalogue

Symbols and Warnings

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CE 2797

Prescription device*
Sterilization using Irradiation
Non-sterile
Caution
Consult instruction for use
Use by date (mm-yy)
Do not reuse
Do not re-sterilize
Batch code
Do not use if package is damaged
Medical Device

* Prescription device: Rx only. Caution: Federal Law restricts this device to sale by or on the order of a licenced physician or dentist.

Canada licence exemption: Please note that not all products may have been licensed in accordance with Canadian law.